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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,415	02/26/2002	Michael J. Pugia	MSE #2645	8582
7590 02:08/2005			EXAMINER	
Elizabeth A. Levy			SIEFKE, SAMUEL P	
Bayer HealthCare LL Two Edgewater Drive Norwood, MA 02062-4637			ART UNIT	PAPER NUMBER
			1743	
			DATE MAILED: 02/08/200	5

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)				
Office Antion Comments	10/082,415	PUGIA ET AL.				
Office Action Summary	Examiner	Art Unit				
	Samuel P Siefke	1743				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status		•				
1)⊠ Responsive to communication(s) filed on 15 Oc	ctober 2004.					
2a)⊠ This action is <b>FINAL</b> . 2b)□ This action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) ☐ Claim(s) 1,5-13,16-18 and 38-50 is/are pending 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1,5-13,16-18 and 38-50 is/are rejected 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	vn from consideration.	; ;				
Application Papers						
9)☐ The specification is objected to by the Examiner	r.					
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
.11) The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents</li> <li>2. Certified copies of the priority documents</li> <li>3. Copies of the certified copies of the priori application from the International Bureau</li> <li>* See the attached detailed Office action for a list of</li> </ul>	have been received. have been received in Application ity documents have been receive (PCT Rule 17.2(a)).	on No d in this National Stage				
Attachment(s)		ı				
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 16/75/04. 10/21/04	Paper No(s)/Mail Da 5)  Notice of Informal Pa 6) Other:	te atent Application (PTO-152)				

Application/Control Number: 10/082,415

Art Unit: 1743

### **DETAILED ACTION**

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **1,5-13,16-18** and **38-50** are rejected under 35 U.S.C. 102(b) as being anticipated by Kellogg et al. (USPN 6,063,589).

Kellogg discloses a device for performing microanalytic analyses that comprises a platform that rotates, thereby utilizing centripetal forces that motivates fluid movement through microchannels embedded in the microplatform. The microplatform comprises sample wells for receiving a sample liquid (col. 10, lines 38-42), capillary passageways communicating with the sample well (col. 10, lines 42-48), passageway including a segment defining the volume of uniform liquid sample being disposed between two intersecting passageways vented to the atmosphere (col. 6, lines 7-14), the segment communicating with a transfer capillary passageway for from a firs sample well to a first reagent well (col. 13, lines 32-38), a capillary stop disposed within the transfer passageway for preventing transfer of uniform sample to the first reagent well (col. 11, lines 7-13). Kellogg discloses the capillary passageways have walls that are hydrophilic relative to the sample liquid (col. 10, lines 64- col. 11, line 8). The capillary stops can either be hydrophilic (col. 10, lines 64- col. 11, line 8) or hydrophobic (col. 11, line 7-13).

Art Unit: 1743

A second and third (multiple) reagent well in liquid communication through a capillary passageway with the first reagent well is disclosed (col. 13, lines 32-38; col. 17, lines 5-20). The first reagent well contains a reagent adapted to react with a component contained in the sample and produce a response indicating the amount of component in the liquid sample (col. 14, lines 5-34) along with reducing the interference of the component with a second component to be detected (col. 17, lines 5-20). The first reagent well contains a reagent to pretreat the liquid sample (col. 17, lines 5-20). Electrodes are disposed in the reagent wells for measuring properties of the liquid sample (col. 53, line 66- col. 54 line 29). The capillary channel has a width of about 10 – 500  $\mu$ m (col. 9, lines 35-41). The capillary passageway has a depth of at least 5  $\mu$ m (col. 9, lines 30-45).

Page 3

## Response to Arguments

Applicant's arguments filed 10/15/04 have been fully considered but they are not persuasive. Applicant argues, "Applicant's system uses only capillary action to fill the segment that defines the amount of the liquid sample. Kellogg's system requires rotating at about 175 rpm to fill the metering capillaries and to empty the inlet well 201 into the overflow channel." Kellogg discloses the use of capillary channels throughout the specification, and a capillary channel uses capillary action to move a fluid through the channel. Kellogg only uses the centrifugal forces to overcome the capillary stop. Therefore all the limitations of the current application are anticipated. Regarding the

**Art Unit: 1743** 

use of hydrophilic capillary passageway and hydrophilic capillary stop, see col. 10, line 64- col. 11, line 8.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Application/Control Number: 10/082,415

Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke

January 6, 2005

Supervisory Patent Examiner Technology Center 1700

Page 5